



**SERNAPESCA**  
Ministerio de  
Economía, Fomento  
y Turismo

**Gobierno de Chile**

FOREIGN TRADE SUB-DIRECTORATE

# Food Safety and Certification Manual



## Part I: Introduction

## 1. OVERVIEW

The Food Safety and Certification Manual, approved through [Exempt Resolution No. 5125](#), of June 29, 2016 (published in the [Official Gazette](#) on July 14, 2016), describes the standards and procedures that ensure the sanitary quality of fishery and aquaculture export products across the entire production chain. It starts with the classification and monitoring of extraction areas, waste control procedures for pharmaceutical products, and unauthorized and prohibited substances in fish farms.

It continues with the procedures to rate the facilities and the sanitary management of fisheries and factory ships that produce export fishery products, as well as the facilities and sanitary control of the production and storage of products for human consumption. It also includes the standards and procedures to rate the facilities and the sanitary control of the production and storage of fish meal and fish oil not intended for human consumption, the general standards and procedures for establishing traceability systems in fish processing plants, and the standards and procedures for risk assessment and critical points control in the production process according to the HACCP methodology.

It describes the necessary procedures to authorize the export of fishery products and to request the issuance of the sanitary and origin certification.

For this purpose, it incorporates the general microbiological, physical, chemical, sensory and toxicological requirements that fishing and aquaculture products must meet to obtain the sanitary certification, per type of hydrobiological resource and per type of destination market. It includes the specific requirements, different from analytic standards, for the export of fishery and aquaculture products to the different export markets, and it describes the standards and procedures to manage the system of laboratories authorized by Sernapesca.

Finally, it includes a section describing the standards and procedures for the sanitary control of hydrobiological resources that enter our country for re-exporting purposes.

## 2. LEGAL BASIS

1. Exempt Resolution No. 5125 of 2016 of the National Fisheries and Aquaculture Service, approving the Food Safety and Certification Manual and its updating process.
2. DFL No. 5, of 1983 and its amendments, of the Ministry of Economy, Development, and Reconstruction, currently the Ministry of Economy, Development, and Tourism, laying down the organic structure of the National Fisheries and Aquaculture Service.
3. SD No. 430 of 1992 (consolidated text of the General Fisheries and Aquaculture Law in Article 122, letter r), empowering the National Fisheries and Aquaculture Service to control the safety of export fishery and aquaculture products.
4. In article 1, paragraph 3, laying down the binding force for the country, to comply with international agreements subscribed by the Republic, regarding the hydrobiological matters or species individualized in the Law.
5. DFL No. 1 of 1992 of MINECON, laying down the roles of the Foreign Trade Sub-Directorate.
6. Exempt Resolution No. 827 of 1993 of the Ministry of Foreign Affairs, laying down the competent bodies for the issuance of certificates of origin.
7. Decree No. 5 of 1985, of MINECON, setting rates for the provision of Services.
8. Regulation (EC) No. 853/2004 of April 29, 2004, laying down specific hygiene rules for food of animal origin.
9. Regulation (EC) No. 2074/2005 of December 5, 2005, laying down implementing measures for certain products under Regulation (EC) No 853/2004.
10. Regulation (EC) No. 1664/2006 of November 6, 2006, amending certain implementing measures for Regulation (EC) 853/2004.
11. Memorandum of Understanding between the Government of Chile and the *Food and Drug Administration* (FDA) of the U.S.A., with regards to the Bivalve Mollusks Sanitation Program in Chile.
12. Directive 2006/88 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals.
13. DFL No. 5, of 1983, of the Ministry of Economy, Development, and Reconstruction, where the following is set forth:
  - Article 25, grants authority to the National Fisheries and Aquaculture Services (SERNAPESCA) to adopt measures and carry out any necessary controls, with the purpose of achieving the effective compliance of the regulations in force.

- Article 28, letter j), the National Director of Fisheries must control the quality of the import and export fishery products, and issue the corresponding official certificates.
  - Article 32, No. 3, letter a) establishes that it is the duty of the Fishing Monitoring and Inspection Department to define and plan monitoring, control and surveillance strategies and actions for each one of the fishing administration standards.
  - Article 32, No. 3, letter b) establishes that it is the duty of the Fisheries Monitoring and Inspection Department to control and inspect extractive agents, fishing vessels, unloading ports and coves, processing plants, cold stores and stockpiling centers, commercialization agents and centers, means of transportation and others that allow to ensure the proper compliance with fishery regulations.
  - Article 32, No. 4, letter h), establishes that it is the duty of the Fisheries Sanitary Department to carry out inspections to verify all the necessary aspects to issue the sanitary quality certification of import and export fishery products, in accordance with the Law.
14. International Agreements where Chile is the contracting or cooperating party, in its role as a port state and/or commerce state.
  15. DFL No. 1 of 1992, of the Ministry of Economy, Development, and Reconstruction, modifying the organic structure of the National Fisheries and Aquaculture Services, where these roles are considered.
  16. Article 122, letter b), of Supreme Decree No. 430 of 1991, which sets forth the coordinated and systematized combined text of the General Fisheries and Aquaculture Law, and its amendments, which establishes the authority of Sernapesca to control the sanitary quality of import food products and of export fishery products, and to issue the corresponding official certificates, as required by the petitioners.
  17. Supreme Decree No. 319 of MINECON approving the Regulation on Protection, Control and Eradication of High-Risk Diseases (HRD) for hydrobiological species.
  18. Decree No. 139 of 1995, of the Ministry of Agriculture (MINAGRI) "Regulation on Pharmaceutical Products Exclusively for Veterinary Use."
  19. Resolution No. 551 of 2014, of the Ministry of Health setting maximum limits of veterinary drugs residues in food for human consumption.
  20. S.D. No. 430/91, General Fisheries and Aquaculture Law.
  21. DFL No. 1 (law 18892) of 1992 modifying the organic structure of the Undersecretariat of Fisheries and of SERNAPESCA.
  22. Regulation No. 319 of August 24, 2001, of the Ministry of Economy, Development, and Reconstruction, establishing the protection, control and eradication measures of high-risk diseases for microbiological species.

23. Council Directive 96/23/EC of April 1996, on measures to monitor certain substances and residues thereof in live animals and animal products.
24. Council Directive 96/22/EC concerning the prohibition on the use in stock farming of certain substances having a hormonal or thyrostatic action and of  $\beta$ -agonists.
25. Commission Decision 98/179/EC laying down detailed rules on official sampling for the monitoring of certain substances and residues thereof in live animals and animal products.
26. Regulation (EC) No. 470/2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No. 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No. 726/2004 of the European Parliament and of the Council.
27. *Specifications and Standards for Foods, Food Additives, etc. - Under The Food Sanitation Law (Abstracts) - Food Hygienic Society of Japan - Jetro.*
28. Regulation (EC) No. 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin.
29. Sanitary Regulations for Food. Ministry of Health, laying down the legal regulations applicable to the control of production, processing, packaging, storage, distribution, sales and import of food in Chile.
30. Regulation No. 16/2012 amending Annex II of Regulation (EC) No. 853/2004.
31. Decree No. 388 of June 27, 2005, on the Regulation for the Substitution of Vessels.
32. Memorandum of Understanding between the Government of Chile and the United States *Food and Drug Administration*, signed in May 1989 and renegotiated in February 2001, where our country commits to ensure the safety of raw bivalve mollusks that are sent to that market.
33. Exempt Resolution No. 302, of 03.29.88, of the Ministry of Health, laying down the duties and obligations of the State bodies involved in the program.
34. Agreement signed between the National Fisheries and Aquaculture Service, the Public Health Institute and the Health Service of Llanquihue, Chiloé, Palena, of 08.16.89. where the mechanisms of action are defined.
35. To export bivalve mollusks to the European Union, in all their forms, the sanitary requirements established by Regulations (EC) No. 854/2004, N° 853/2004, Decisions 2003/804/EC and 2004/623/EC, and their amendments must be met.
36. The legal authority of SERNAPESCA to delegate the inspection, sampling, analysis and charging to the authorized entities is set forth in Article 122 r, paragraph 2 of the Law on Fisheries and Aquaculture. In turn, the authority to control the operation of these procedures is outlined in Article 32 J, letter b of DFL No. 50 of 1983 and its amendments, of

the Ministry of Economy, Development, and Reconstruction, currently the Ministry of Economy, Development, and Tourism.

### 3. PURPOSE

Describe the standards and procedures to control the safety of export fishery and aquaculture products, in the different stages of the production chain.

### 4. SCOPE

The Food Safety and Certification Manual comprises the work of SERNAPESCA on safety control for export fishery and aquaculture products across the entire production chain, from the control of origin to the production, and the export process. It also describes the requirements for importing fishery products.

## 5. GLOSSARY

**Corrective Actions:** The procedures to be followed when a critical limit is reached or exceeded, with the purpose of returning the process to control and avoid the production of defective products.

**Crude Fish Oil and its By-products:** Corresponds to the fat content of fish coming from the transformation in fishmeal production industries as crude oil and the by-products of its industrial process through the application of physical and/or chemical processes, with the purpose of modifying its properties.

**Conditioning:** The storage of live bivalve mollusks coming from "class A" production areas, depuration centers or dispatch centers in tanks or any other installation containing clean seawater, or in natural sites, to remove sand, mud or slime, to preserve or to improve organoleptic qualities and to ensure that they are in a good state of vitality before wrapping or packaging.

**Accreditation of Legal Origin:** Process where it is accredited through documents that the fishery products have been caught, harvested or processed in compliance with national and international fisheries and aquaculture regulations applicable in the country of origin.

**Water Activity (aw):** Measure of free humidity in the product and the ratio between the vapor pressure of the product, divided by the vapor pressure of pure water at the same temperature. A term that expresses a general measure of the availability of water for microorganisms. It is defined as  $p/p_0$ , where  $p$  and  $p_0$ , respectively, are the vapor pressures of the microbial substrate (food, solution or microbiological media) and of pure water.

**Additives:** Natural or synthetic elements and their combination, that are added to food for the purpose of improving their presentation, changing their organoleptic characteristics or to create specific effects in the species for which they are intended.

**Mollusks Concession Groups/MCG-BMSP:** Group of two or more BMSP areas that share a geographic and oceanographic zone of similar characteristics that allow elaborating a common monitoring program.

**Clean Seawater:** Natural, artificial or purified water or salt water that does not contain microorganisms, noxious substances or toxic marine plankton in quantities that could directly or indirectly affect the sanitary quality of food products.

**Clean Water:** Clean seawater and fresh water of a similar quality.

**Potable Water:** All water that is used in the fishing industry, not including seawater or water coming from the local water supplier. This type of water must be treated so as to comply with the limits of NCh 409/1 of 2005.

**Acidified Food:** Low-acid food to which acid or acid ingredients are added to reduce their pH. These foods have a water activity (aw) greater than 0.85 with a finished equilibrium pH below 4.6.

**Complete Food:** Mix of nutritional ingredients, with or without additives, capable of satisfying nutritional requirements of the species for which they are intended.

**Low-acid Food:** Any food, with a finished equilibrium pH above 4.6 and with a water activity ( $a_w$ ) greater than 0.85.

**Private Bonded Warehouse:** A secured storage facility specifically indicated in the destination document, where import goods remain under custom's authority, without payment of duties or taxes.

**Hazard Analysis:** Process of collection and assessment of information on the hazards and the conditions that cause them to decide which are significant for food or feed safety.

**Decision Tree:** A logical sequence of questions made in every stage of a process, on whether a significant hazard is a control point associated with the stage.

**Extraction area:** Geographic area from which marine resources are extracted for further processing in a fishery plant or dispatching from a distribution center.

**Entry and Preparation Area in Loading/Unloading Site:** The Entry and Preparation Area is an independent area, however, attached to the operation and/or inspection chamber where the staff, wearing appropriate equipment, will enter to inspect loads.

**Inspection Area in Loading/Unloading Sites:** Inspection area is the isolated sector of the operation chamber where boxes containing goods will be taken for a thorough inspection, thus becoming the inspection room.

**Management and Exploitation Area for Benthic Resources/MEABR:** Access regime that assigns exploitation rights exclusively to Artisanal Fishermen Organizations, through a management and exploitation plan based on the conservation of benthic resources present in previously delimited geographic sectors.

**Operation Area in Loading/Unloading Site:** The operation area in which the loads taken from the container under inspection will be placed to select those boxes or units to be checked in the inspection rooms.

**BMSP Area:** Extraction area, comprised of mollusks farms, natural banks or MEABRs, that comply with the Bivalve Mollusks Sanitation Program (BMSP).

**Self-certification:** An authorized means of origin certification which is used only under certain trade agreements where the exporter, the importer, or the producer itself, declares that the goods being exported to a certain market comply with the standards of origin outlined in the corresponding Trade Agreement.

**Autoclave:** Any type of closed container or other equipment used for thermal processing of food.

**Competent Authority:** National Fisheries and Aquaculture Service.

**Process Authority:** Person or organization with expert knowledge in thermal processes for food in hermetically sealed containers, with the necessary equipment and facilities for carrying out such processes, and which is appointed by the institution to carry out certain functions described in this Manual.

**Regional Health Authority:** Regional representative of the Ministry of Health, with authority in the area of public health.

**Authorization at Origin for Sanitary Certification/AOSC:** Document that certifies that the products set forth therein have been produced in a facility with an appropriate quality assurance program, and therefore can obtain a sanitary certification for specific markets. This document is authorized by the Sernapesca office with jurisdiction over the relevant facility.

**Marine Biotoxins:** Poisonous substances accumulated by bivalve mollusks feeding on plankton containing toxins.

**Blower:** A receptacle for washing shucked shellfish which uses forced air as a means of agitation.

**Warehouse:** Facility or installation in which processed products are stored temporarily before their use.

**Factory Ship:** A processing vessel in which fishery products are subjected to one or more of the following operations before packaging: Filleting, slicing, skinning, chopping, freezing, and transformation. Fishing vessels which only cook and freeze crustaceans and mollusks on board are not considered to be factory ships.

**Artisanal Fishing Cove:** Coastal geographical area where artisanal fishing activities take place. The term Cove is considered to be a synonym of an unloading area (fishing cove, anchorage, breakwater, pier, dock, esplanade).

**Calibration:** Set of operations that establish, under specified conditions, the relationship between the values delivered by a measuring device or by a measurement system, or the values represented by a physical quantity or reference material and the corresponding values of a magnitude carried out by a reference pattern.

**Cold Room:** An area built with thermal insulation material, to preserve perishable products at low temperatures.

**Fishing Bait:** Fishing product used as lure in extractive fishing activities.

**Land Waybill:** Document provided by the parties in a contract to accredit the existence and conditions of transportation.

**Harvesting or Stockpiling Center:** A premise intended for temporarily storing hydrobiological resources coming from farms or authorized extractive activities, for their further commercialization or transformation.

**Farm:** Area or building where aquaculture activities take place.

**Distribution Center:** Any approved onshore or offshore installation for the reception, conditioning, washing, cleaning, grading and wrapping of live bivalve mollusks fit for human consumption.

**Depuration Center:** Approved establishment with tanks fed by clean seawater, in which living bivalve mollusks are kept during a period of time necessary to reduce their contamination with the purpose of making them fit for human consumption.

**Sanitary Certification:** Is the procedure by which official certification bodies and officially recognized bodies provide written or equivalent that foods or food control systems conform to sanitary requirements.

**Certification:** In the QAP (Quality Assurance Program) it refers to the issuance of a certified number for a given company, meaning that it complies with the requirements of the Standard. Certifications must be revalidated every calendar year.

**Certificate of Accreditation of Legal Origin:** Document that accredits that the fishery products have been obtained, caught, harvested or processed in compliance with national and international fisheries and aquaculture regulations applicable in the country of origin.

**Customs Destination Certificate (CDA - CDC):** Document issued by the Health Authority, which authorizes to move the goods from the customs facilities and store them in a destination warehouse, stating the routes and means of transportation, until the use and consumption authorization is issued.

**Certificate of Origin:** Document that accredits the origin of the goods, for the purpose of applying preferential, non-preferential tariff duty rates, quotas and any other measures established by law.

**Sanitary Certificate:** Official document from the Government of Chile, issued by the National Fisheries and Aquaculture Service that certifies the sanitary conditions of the goods described therein.

**Client:** For the purpose of this Manual, it refers to the company or natural person who acts as the next link in the distribution chain, and that handles or commercializes food produced by a processing facility.

**Fish Protein Concentrate:** Concentrated product derived from fish silage, and which is obtained after the de-fatting process, it refers to the hydrolyzed and concentrated fish protein.

**Condensation:** Humidity accumulated in ceilings, walls, overhead installations, piping or other surfaces.

**Bill of Lading (B/L):** Document that proves the existence of a maritime transportation contract and confirms that the goods have been shipped aboard a vessel.

**Canning:** The process of packaging products in sealed airtight containers to then subject them to a thermal process for enough time to destroy or inactivate any microorganisms that may proliferate, regardless of the temperature in which the product will be finally stored.

**Cross-contamination:** Transfer of biological or chemical contaminants to products, coming from raw materials, food handlers or the environment inside the processing room. // Unprotected connection, current or potential, between a potable water system and a fountain or system that contains non-approved water or a substance that is not or cannot be approved as safe and potable.

**Contamination:** The presence of microorganisms, viruses and/or parasites, foreign or deleterious matter of mineral, organic or biological origin, radioactive substances and/or toxic substances in levels above those allowed internationally, or that are presumed to be harmful to health. The

presence of any kind of soil, residues or feces. Non-authorized additives or in levels above those permitted.

Contaminant: Substance coming from industrial activities in general, pesticides and toxic elements or other chemical substances contained in water where fish are kept, and that can accumulate in their flesh, at levels that may cause harm to the consumer.

Cold Container: Structure with standardized dimensions and with devices that allow preserving perishable products, protected from atmospheric agents and with a minimum level of handling.

Counter Sample: Part of the extracted sample, which must be separated and stored in the analysis laboratory.

End Product Control: Methodology established to guarantee the sanitary condition of a manufactured product ready to be sold, through its analysis by a laboratory authorized by SERNAPESCA, as per the requirements of the product and the destination market.

Frozen Crustaceans: Whole crustaceans or in pieces, peeled or in their shell, cooked or raw, that have been subjected to a freezing process.

Thermal Shock: Process in which bivalve mollusks are subjected to any type of thermal treatment before shucking, which includes steam, hot water or dry heating, to facilitate the removal of the meat from the shell without substantially altering their physical characteristics.

Declaration of Guarantee: Document that the farm must issue for each fish lot that enters the processing plant. This document certifies that the raw materials assigned to the process do not contain any Pharmaceutical Products residues in quantities exceeding the Maximum Limits required by the destination markets and that they do not contain Prohibited and Unauthorized Substances.

Declaration of Entry (*D/IV* - DOE): Document formalizing a customs destination, and which must indicate the class or type of destination in question.

Sworn Declaration of Origin: Written document that states the origin of the harvested goods under oath.

Critical Deficiency (CR): A deficiency that does not comply with the requirements for the facility's infrastructure, health management of the process and/or the safety of the product, thus producing foodstuff that is a threat to public health.

Minor Deficiency (MN): It is not aligned with the requirements for the facility's infrastructure, health management of the process and/or the safety of the product, and its impact on food slightly affects general hygiene.

Major Deficiency (MJ): Does not comply with the requirements for the facility's infrastructure, health management of the process and/or the safety of the product, thus reducing its quality, without becoming Severe.

Severe Deficiency (S): The facility does not have the proper infrastructure, neither a correct health management system for the process and/or product safety, which can lead to the alteration of food.

**Algae By-products:** Products obtained through industrial processes, which are used in the food, pharmaceutical and cosmetics industry, such as Agar-Agar, Alginate, Carrageenan, and Colagar, among others.

**Landing:** Process of unloading fishery products in artisanal coves, docks, pontoons, etc.

**Disinfection:** Process used to reduce the number of microorganisms to a level that does not allow a harmful contamination of food, without affecting its quality, through chemical agents and/or proper sanitation methods.

**Disinfectant:** Chemical product used by the corresponding Ministerial Regional Secretariat of Health, to eliminate or reduce potentially harmful bacteria.

**Process Deviations:** Any variation in the formulated process caused by changes in the conditions established for it, such as critical factors or other operating conditions of the devices involved in the sterilization process.

**Flow Chart:** Systematic and sequential graphic representation of the stages or operations for manufacturing food.

**Single Exit Document (DUS - SED):** Document which lists the goods before the National Customs Service for its further shipment abroad. For this document to obtain the "authorized to exit" status the Notification of Shipment of Export Fishery Products (NEPPEX) is required.

***E. coli:*** Fecal coliforms which also form indole from tryptophan at 44 C° + 0.2 C° within 24 hours.

**Elasmobranchii:** Ray (*Raja spp*); Shark or Mako (*Isurus oxyrinchus*), Speckled Smoothhound (*Mustelus mento*); Blue Shark (*Prionace glauca*); Common Thresher Shark or Fox Shark (*Alopias vulpinus*); Cockfish (*Callorhynchus callorhynchus*).

**Packaging:** The operation through which live bivalve mollusks are placed in a package that is suitable for this purpose.

**Packaging or packing:** The operation intended to protect fishery products through a wrapping, a package or any other suitable material.

**Vessels:** For the purpose of this Manual, the following will be considered as vessels:

1. Boat: Vessel with incomplete deck, with or without a jet engine.
2. Small-sized Boat: Vessel with a full deck and jet engine, with no more than 12 meters of length.
3. Mid-sized Boat: Vessel with a full deck and jet engine, between 12 and 15 meters of length.
4. Large Boat: Vessel with a full deck and jet engine, between 15 and 18 meters of length.
5. Industrial Vessel: Vessel with more than 18 meters of length and that does not qualify as a factory ship.

**Fish Sausages:** Raw or cooked sausages made with fish flesh, such as fish sausages, smoked fish sausages, fish ham, and salami.

High-Risk Diseases (*EAR* - HRD): Deviation of the complete state of physical well-being of an organism, which involves a well-defined set of signs and etiology, leading to a severe limitation in its normal functions, associated with high mortality and of transmissible nature to organisms of the same or different species. The list of these diseases is detailed in Resolution No. 1741 of June 9, 2013, of the Undersecretariat of Fisheries and Aquaculture (Regulation No. 319, on protection, control and eradication measures of high-risk diseases).

Fish Silage: A mix mainly comprised of fish or fish parts with the addition of preservatives, most commonly formic acid.

Analysis Entity: Laboratory, either private or public, authorized to perform chemical and microbiological analyses and sensory evaluation.

Sampling Entity: Public or private institution authorized by SERNAPESCA to perform samplings and inspections to export fishery products.

Primary Packaging: Container, package or wrapping in direct contact with the product that ensures its preservation, and facilitates its transportation and handling.

Secondary Packaging: Container, package or wrapping to hold pre-packaged parts that are enclosed in the primary packaging.

Shipment: The number of live bivalve mollusks handled in a distribution center, treated in a depuration station or processed in an approved establishment, aimed at one or many clients.

Measurement Device: All measurement instruments, measurement patterns, reference materials, auxiliary devices and instructions that are necessary to take measurements. This term includes measurement devices used for trials and inspections and also those used for calibration.

Systematic Error: Average readings of the object being calibrated minus the actual corrected value defined by SERNAPESCA or those required by the different destination markets.

Slaughterhouse: Facility or establishment for slaughtering, bleeding and eventual evisceration of hydrobiological resources to be sent to a processing plant.

Reduction Plant: Fish processing plant or factory vessel in which only fishery or aquaculture products are transformed; mixing and/or reprocessing activities are carried out in products such as fish oil and fish meal, peptones, crustacean meal, protein concentrate, and fish silage, among others.

Certification Standard: Tolerance that one or more characteristics assessed must comply to confirm the quality of the product.

Commercial Sterility: The conditions achieved by application of heat which renders such food free from microorganisms capable of growing at temperatures at which the food is likely to be held during distribution and storage, not refrigerated and free of viable microorganisms (including spores) of importance for public health.

**Temperature Distribution Study:** Evaluation of temperature inside the autoclave and its distribution. The purpose of this study is to identify the worst expected situation that may take place in a commercial production influenced by the product, packaging, and process.

**Heat Penetration Study:** Consists in determining the behavior of warming and cooling of a product and its packaging in a specific autoclave system, to establish a safe thermal process and evaluate its deviations.

**Sensory Evaluation:** The examination of the physical attributes or characteristics of a product that can be analyzed through the sense organs. It is the procedure through which the sanitary quality of the cooled refrigerated and live fishery products is evaluated.

**Export:** Legal exit of national or nationalized goods for their use or consumption abroad.

**Easily Washable:** Readily accessible surface. Is made of such materials has a finish and is so fabricated that residues may be effectively removed by normal cleaning methods.

**Critical Factor:** Any property, characteristic, condition, aspect or parameter whose variation may affect a formulated process and the scope on commercial sterility. Critical factors must be incorporated in the descriptions of the plants' **Quality Assurance Programs**.

**Production Date:** Code that indicates the date in which the product was transformed, reprocessed, refined or subjected to mixing, as appropriate; date in which the fishery product is transformed, thus becoming the product described on the packaging or label.

**Expiration Date or Term:** The date or term in which the manufacturer states that, under certain storage conditions, the period in which the product keeps its expected quality attributes ends. The product cannot be commercialized after this date or term.

**Date of Entry of Goods:** Date in which the goods arrive at the national territory.

**Treatment Group:** Represents a group of fish in a farm, clearly identifiable, which may be comprised of one or more cages or ponds that have been subjected to the same pharmaceutical management conditions. That is those fish of the same species that have received treatment during the last 6 months with the same active principle, dosage and start and end dates.

**Non-Treated Group:** Shall be understood as groups of non-treated fish that have not received treatment during the last 6 months.

**Air Waybill:** Document that serves as a contract of air carriage.

**Fish Meal:** Transformed animal protein, derived from marine animals, except mammals.

**ICSSL, *Interstate Certified Shellfish Shippers List*:** An FDA publication on all the national and foreign plants that have been certified by state or international authorities, in compliance with the requirements of the program.

**Inspection Batch Identification:** It must include the production code, comprised of the date of production (numerical or alphanumeric system) followed by letters or digits that allow

individualizing the inspection batches from the same date of production. Similarly, the tonnage of the batch, as well as its inspection lots shall be specified.

**Lot Identification:** It must be identified with the production code, comprised of the date of production (numerical or alphanumeric system) followed by letters or digits that allow individualizing the inspection batches from the same date of production. This code must be printed in the sack or on the individual label. In the case of containers, the production code must be printed in a visible area.

**Import:** Legal entry of foreign goods into national territory for local use or consumption.

**Importer:** Natural or legal person who files importing documentation or conducts importing formalities, either in person or through third parties.

**Increment:** Quantity of fish meal collected from an inspection lot at one time with a probe or spear.

**Ingredient:** Product of natural or synthetic origin that acts as a nutrient.

**Entry:** Introduction of goods into national territory, including importing, re-importing, re-entry, rejections and primary zone storage.

**Registration of a Processing Plant:** Registration of a processing plant in the register managed by the National Fisheries and Aquaculture Service through Exempt Resolution, and that enables the raw material reception plant, either of national or foreign origin, to process or reprocess fishery products in certain processing lines.

**Inspection:** Examination of food products or food control systems, raw materials, processing, and distribution, including in-process and finished product testing, to verify that they conform to requirements.

**Standardized Plant Inspector:** Person who has successfully completed the training courses taught by the *Food and Drug Administration* and the evaluation phase of on-site plants with other FDA standardized officer.

**Measuring Instrument:** Device for measuring, to be used independently or together with other devices.

**Entry:** Process of obtaining authorization for the distribution, use, and consumption of the imported product.

**Inspection Item:** One of the standardized criteria, listed in the "Standardized Inspection Checklist for BMSP Processing Plants," which includes single or several notes on critical, key or other deficiencies.

**Analysis Laboratory:** Laboratory authorized by SERNAPESCA to carry out analyses and issue the corresponding reports to be used as supporting documentation for the Declaration of Guarantee.

**Fish Processing Plant Laboratory:** The private laboratory of a fish processing plant, authorized by SERNAPESCA, which provides fishery products analysis services for process control, regular checks, as well as for monitoring the raw materials of the processing plant where it belongs.

**Service Laboratory:** Private laboratory, authorized by SERNAPESCA, which provides analysis services to farms, fish processing plants and fishery products companies.

**SERNAPESCA Verification Laboratory:** Analysis entity linked to the public or private sector, recognized by the Service to carry out analyses referred to verifications, as described in the Food Safety and Certification Manual, and that provides such analysis services exclusively to SERNAPESCA.

**International Reference Laboratory:** International laboratory appointed by SERNAPESCA to act as a reference laboratory in the context of dispute resolution in the results of analyses.

**Hauling Boat:** An artisanal vessel that hauls the catch of other vessels to the port.

**Maximum Residual Limit (MRL):** Maximum acceptable concentration of residue in food resulting from the use of a veterinary drug. It is based on the type and amount of residue that do not represent a toxicological hazard to human health as expressed by the Acceptable Daily Intake.

**Lower Limit (m):** A microbiological criterion which, in a two-class program, separates the acceptable from the rejectable quality or, that in a three-class program, separates acceptable quality from temporarily acceptable quality. In general, m represents an acceptable level, and the values above it are temporarily acceptable or unacceptable.

**Cleaning:** Elimination of dirt, meal residues, dust, grease or other unacceptable matter.

**Inspection Lot:** The amount of fish meal in any form of up to 50 tons, whose biological, physical and chemical characteristics are presumed to be uniform. In the case of fish meal packed in containers, the inspection lot corresponds to the container.

**Lot of Mollusks in Shell (Raw Material):** A unique type of mollusks that have been extracted in a period no longer than a day, from a defined growth area.

**Lot:** The number of fishery products obtained under practically identical circumstances. // The number of live bivalve mollusks handled in a distribution center, treated in a depuration station or processed in an approved establishment, aimed at one or many clients. // The number of food units produced and handled under uniform conditions, over a certain period. The number of units or quantity of product which comprise the lot is called lot size (N). // Fish that enter a fish processing plant, over the course of one day, coming from the same farm, and belonging to a same treated or non-treated group. Each lot may be comprised of one or more cages or ponds or parts of them. // Homogeneous set of containers or primary units, of similar weight, type, and class, processed under similar conditions, during a day of work, which is identified with a production code.

**Magnitude:** Common quality of the measurable quantities of the same species.

**Controlled Atmosphere Preservation (CAP):** Process through which a packed product is subjected to modified environmental conditions, that is to say, subjected to an environment with different combinations of gases, thus extending the life of the product, and without any handling. // For the purpose of this standard, cold room facilities will be considered as cold stores, and cold containers will be considered as cold chambers (Section II, Part II, Chapter I, Item 3.)

**Raw Material:** Any hydrobiological species or by-products obtained through landed, caught, collected, harvested or imported fishing and aquaculture, intended for a certain transformation process. The products or by-products of some processing lines may be considered as raw materials for other lines.

**Category 1 Material:** This material includes:

- By-products and derivatives of animals treated with prohibited or unauthorized substances, as per the national or community legislation.
- Animal by-products that contain residues of other substances and environmental contaminants, such as organochlorine and organophosphate pesticides, chemical elements, mycotoxins, and colorants, among others.
- By-products collected during waste water treatment of facilities or plants that process Category 1 material.
- The mix of the material of category 1 with category 2, with the material of category 3, or both.

**Category 2 Material:** This material includes:

- By-products collected during waste water treatment of facilities or plants that process Category 2 material.
- Animal by-products and derivatives that contain residues of authorized substances or contaminants that exceed the levels outlined in the national or community legislation.
- Products of animal origin that have been declared as unfit for human consumption due to the presence of foreign bodies.
- Animals and animal parts, different from those included in category 1 and 3, that died or that have been slaughtered for human consumption, including animals slaughtered for disease control purposes.
- A mix of category 2 with category 3.
- Animal by-products other than those of category 1 or 3.

**Category 3 Material:** This material includes:

- Aquatic animals and their parts, except marine mammals that do not show evidence of diseases transmittable to humans or animals.
- By-products of aquatic animals coming from establishments that manufacture products for human consumption.
- The following material of animals that do not show evidence of diseases transmittable to humans or animals through such animals, such as mollusk shells and crustacean shells with soft tissue or meat.
- Aquatic invertebrates, except pathogenic species for humans or animals.

**Packaging Material:** All containers such as cans, bottles, cardboard boxes or other materials, covers and sacks, or materials to wrap or cover, such as laminated paper, film, waxed paper, fabric.

**Corrosion Resistant Material:** Material that keeps its original characteristic surface under regular exposure to food, regular use of cleaning solutions and antibacterial solutions, and other use conditions.

**Measurement:** Set of operations whose purpose is to determine the value of a magnitude.

**Preventive Control Measures:** Any action that reduces the occurrence of hazards to acceptable levels.

**Means of Transportation:** The freight-carrying parts of motor vehicles, aircraft and the hold of ships or containers for transport by land, sea or air.

**Measured:** Magnitude of a measurement.

**National Goods:** Goods produced or manufactured in the country with national or nationalized raw materials.

**Nationalized Goods:** Foreign goods whose import has been legalized, after the tax formalities are completed, and are then at the free disposal of the interested parties.

**Goods:** Within the scope of SERNAPESCA, it comprises the different elements that can be entered into the country, which correspond to the following: Products derived from hydrobiological resources, feeds intended for aquatic species, biological material, pathological material, material, and equipment for aquaculture, and live hydrobiological species.

**Mix:** Part or volume of fish meal or oil comprised of previously transformed product, coming from two or more transformation processes, of one or more facilities.

**Mixes of Sources:** Act of combining lots of raw material or shucked product.

**Bivalve Mollusks:** Lamellibranchia mollusks fed by filtration. Includes gastropod, tunicates, and echinoderms.

**Monitoring:** Execution of scheduled tests or observations, that are recorded by the executor to inform the results of the controls established in every critical control point.

**Dock:** A structure extending from a shore over water, and used for docking large vessels and where passengers can get on or off a vessel or where goods can be put on and taken off.

**Representative Sample:** Amount of fish meal extracted from an inspection lot which reflects its biological, chemical and physical characteristics.

**Sample:** Set of product units that are extracted and that are representative of a batch, in which the corresponding analyses take place. The number of sample units is called sample size (n).

**Commercial Samples:** Lots of up to 20 kilograms of products that are imported for the purpose of carrying out tastings, scientific research or that are intended for family consumption.

**Official Sampler of Export Fishery Products:** Staff authorized by SERNAPESCA, belonging to an authorized sampling entity, that has completed and approved an official course for samplers.

**Sampling:** Process used to extract or obtain a sample. It must be representative, extracting units randomly.

**Acceptance Limit Level (m):** The microbiological criterion that, in a three-class program, separates the temporarily acceptable quality from the rejectable one. Those values equal to, or above M, are not acceptable.

**Notification of Shipment of Export Fishery Products (NEPPEX):** Form to request authorization to export fishery products before the National Fisheries and Aquaculture Service.

**Acceptance Number (c):** Maximum number of defective units that can be found in a sample to accept the lot from which it was extracted.

**Certification Number:** Exclusive identification for a company and a plant, provided by SERNAPESCA, to export raw bivalve mollusks to the United States.

**Main Panel:** Most appropriate part of a label to be displayed, exhibited, shown or examined under regular conditions for retail sale.

**Visible Parasite:** Parasite or group of parasites with a size, color, and texture that allow to clearly distinguish it from the tissue of the fish, mollusk or crustacean.

**Import Batch:** Set of products that enter the country through one step of the customs formalities.

**Inspection Batch:** Quantity of fish meal in bulk comprised of one or more inspection lots of the same production date and which is set up forming a pile.

**Product Batch:** Units or quantity of the product of one or more lots that comprise a shipment.

**Measurement Pattern:** Physical measurement, a measurement device, reference material or system whose purpose is to define, conduct, save or reproduce a unit or one or more values of a magnitude to transmit them by comparing them with other measurement instruments.

**Hazard:** An unacceptable biological, chemical, physical or economic characteristic in a product that may affect the consumer.

**Frozen Fish and Cephalopods:** Those raw or cooked fish and cephalopods that have been subjected to cold until reaching a temperature of  $-18\text{ C}^{\circ}$  in the center of the product. Ultra-fast-freezing or fast-freezing products are considered in this group.

**Pests:** Insects, rodents, birds or other minor species capable of directly or indirectly contaminating food.

**Sampling Plan:** Establishes the sample size (n) that must be inspected in each lot and the criteria to determine its acceptability. // Indicates the number of product units that must be inspected, according to the category of the plant, the presentation of the product and the criteria to determine its acceptability.

**Slaughter Plant:** An inland facility where live fish arrive to be slaughtered, which consists of a desensitization process for their further bleeding by cutting their guts and eventual evisceration, to be then sent to a processing plant.

**Primary Plant:** Processing plant in which hydrobiological resources are prepared and/or transformed, that is to say, those plants where preliminary operations take place.

**Fishery Plant:** Any premise where fishery products are prepared, transformed, refrigerated, frozen, packed or held. Those premises that only store fishery products will not be considered fishery plants.

**Ready Cooked Meals:** Fish based food, whose preparation includes ingredients other than fishery products, and that is offered to be consumed without any other preparation but cooking.

**Pontoon:** Structure installed in the sea to receive the catch from small-sized vessels.

**Probability of Occurrence:** Frequency in which an identified hazard may take place.

**Product Removal Procedure:** Coordinated, efficient and timely actions to recover defective products (due to food safety issues) that are no longer with the manufacturer.

**Formulated Process:** Also known as the programmed or established process, which is the necessary process to ensure the destruction of microorganisms of interest for public health, established by a competent process authority to achieve the commercial sterility of a specific product, with the critical factors associated with this product and to this process.

**Operational Process:** Process selected by the processing company, that equals or exceeds the minimum requirements outlined in the formulated process.

**Process:** One or more actions or operations such as catching, processing, storing, dispatching, shipping and distributing a product.

**Alternative Processes:** Those processes established by the process authorities as equivalent to the formulated process and that must be applied whenever deviations in the sterilization process take place. (See CTT Program.)

**Primary Production:** Is the production, breeding or farming of primary products before their slaughter.

**Pharmaceutical Product Exclusively for Veterinary Use:** All natural or synthetic substances or their combination, which under a certain pharmaceutical form, are intended for the prevention, diagnosis, cure, treatment, and relief of animal diseases or their symptoms. This concept includes products intended to medicate food, stimulate the development of animals, their embellishing, environmental or equipment disinfectants, and any other products that when used in animals or in their habitat, protect, restore or modify their organic or physiological functions.

**Food Products:** Products that fall within one of the following categories: Complete food, ingredient, supplement or additives.

**Product Fit for Human Consumption:** Product that has been evaluated and that accredits food safety characteristics, due to which it can be consumed by the human population.

**Product with Zoosanitary Risk:** Product intended for transformation and made from the species described as susceptible to High-Risk Diseases indicated in the official documents of the World Organization for Animal Health (OIE), Sanitary Code and Techniques Manual. The following are not included in this definition: Products intended for human consumption, processed and packed for direct retail sale, and wholesale products to the extent that they are not subjected to any other transformation process by the wholesaler or retailer, that is to say, that they are not cleaned, filleted, frozen, thawed, cooked, unpacked, packed or repacked.

**Product Unfit for Human Consumption:** Product that was processed to be consumed by animals, or whose safety analysis does not authorize it for human consumption.

**Live Fishery Products:** Those that are offered alive, in their natural state.

**Cooked Products:** Those that have been subjected to the action of steam, boiled water or other appropriate procedure, reaching a temperature above 70 C° at its coldest point.

**Frozen Products:** Those fishery products that have been subjected to a thermal process until reaching an internal temperature of at least -18 C°, after thermal stabilization.

**Raw Products:** Those that have not been subjected to intense thermal treatments or that have been subjected to thermal treatments that are insufficient for them to be considered as cooked products, as per the previous definition.

**Aquaculture Products:** All fishery products born and raised in controlled conditions until placed on the market as a foodstuff. Marine and freshwater fish and crustaceans caught in their natural environment during young phases and that are kept in captivity until reaching the intended commercial size are also considered aquaculture products. Fish and crustaceans of commercial size caught in their natural environment and kept alive to be placed on the market, are not considered to be fishery products, to the extent that the only purpose for their stay in ponds is to keep them alive and to increase their size or weight.

**Surimi Products:** Products made with surimi base and other ingredients which are mixed, pumped and extruded, cooked, dried, shaped, cooled, stored and packed. They consist of unique food with flavors that are similar to the natural flavors of the species of lobsters, prawn, shrimp and other crustaceans.

**Fish silage By-products:** Fishery products obtained from fish silage processing, mainly referred to fish oil and fish protein concentrate.

**Fresh Products:** Whole or ready-made fishery products, including those products packed under controlled atmosphere, which have not been subjected to any type of treatment different from refrigeration intended to guarantee their preservation (temperature between 0 and 4 C°.)

**Smoked Fishery Products:** Those that, whether previously salted or not, are subjected to the action of the smoke of woods suitable for these purposes, and that are ready to be consumed. This definition includes those smoked products whose presentation is fresh or frozen.

**Breaded Fishery Products:** Those products made with fishery products, coated with bread crumbs, flour or other ingredients necessary for this presentation.

**Canned Fishery Products:** Products in hermetically sealed containers that have been subjected to a thermal treatment that guarantees their commercial sterility and that ensures their preservation at normal storage and distribution temperatures.

**Fresh Refrigerated Fishery Products:** Those whole or eviscerated, shucked, headless fishery products or in pieces that have not been subjected, since being caught, to any preservation processes other than refrigeration (temperature between 0 and 4 C°.) Those products that have been subjected to a cold shock, reaching a temperature of up to -3 C° on the surface of the product (*super chilling*) are also included under this concept.

**Preserved Fishery Products:** Preserved products are those fishery products or their preparations that are preserved in vinegar or fermented products.

**Refrigerated and Processed Fishery Products:** Those processed products in any of the previously described presentations herein, which are kept refrigerated until their final consumption.

**Salted Fishery Products:** Those subjected to the action of food-grade salt, either solid or in brine, together with other spices and whose minimum content of sodium chloride is 15%.

**Dried Fishery Products:** Those subjected to the action of dry air or any other type of procedure to obtain 10% of moisture or less.

**Salted and Dried Fishery Products:** Those products subjected to combined treatments of mechanical dehydration and the addition of salt, achieving a water activity of 0.85 or less.

**Fishery Products:** All marine or freshwater animals or animal parts, including eggs. Aquatic mammals are excluded. // Hydrobiological resources or their by-products, subjected to entry or import, except live species.

**Ready-made Products:** Fishery products that have been subjected to a modification in their anatomical integrity, for instance, evisceration, de-heading, slicing, filleting, etc.

**Primary Products:** Products of primary production, that is to say, products that are commercialized in the state in which they are in nature.

**Chemical Products:** Includes products used for cleaning and disinfection, sanitizers, lubricants, pesticides, and rodenticides or other chemicals used in the company and that constitute a potential contamination hazard for fishery products.

**Quality Assurance Program (QAP):** Voluntary sanitary control program, which based on a hazard analysis and critical points control, allows ensuring the quality of the end product.

**Pharmaceutical Products, Contaminants, Prohibited Substances and Unauthorized Substances Residues Control Program/FAR:** Program whose aim is to guarantee the food safety of products made with farmed fish, regarding the concentrations or presence of pharmaceutical products, contaminants, and prohibited substances.

**Bivalve Mollusks Sanitation Program/BMSP:** Sanitary program which aims to guarantee the sanitary quality of export bivalve mollusks through the classification and monitoring of extraction areas; and is extensive to echinoderms and marine tunicates.

**Placement on the Market:** The possession or exhibit for sale, the sale, delivery or any other means of sale in the live bivalve mollusks market either raw for human consumption or for its transformation in the community.

**Critical Control Point (CCP):** Any operational step in food processing, where the lack of control may immediately cause a product to represent a safety or health hazard.

**Control Point:** Any operational step in a process that involves some kind of hazard.

**Container Storage Premises:** Physical delimited and restricted area in which cold containers are kept or which has facilities for connection to power supplies for cold containers.

**Gatherer:** Any natural or legal person who collects live bivalve mollusks by any means from a harvesting area for the purpose of handling and placing on the market.

**Re-packaging:** The operation intended to change the protection of fishery products by changing its wrapping, a package or any other suitable material.

**Re-export:** Return to another country of goods brought to the country and nationalized.

**Refinement:** Comprises physical and/or chemical processes applied to oil with the purpose of modifying its properties. It also includes processes such as winterization, esterification or others.

**Refrigeration:** The process of lowering the temperature of fishery products until it is close to ice melting.

**Re-entry:** Return of national or nationalized goods to the national territory (Glossary of Foreign Trade Terms - National Customs Service).

**Relaying:** An operation whereby live bivalve mollusks are transferred to approved sea or lagoon areas or approved estuarine areas under the supervision of the competent authority for the time necessary to remove contamination. This does not include the specific operation of transferring bivalve mollusks to areas more suitable for further growth or fattening.

**Reprocessing:** Corresponds to the transformation activity that uses raw material as a product previously subjected to transformation, in which the characteristics defined for such product were not accomplished, and therefore the product is reintegrated to the same processing line or to another one to achieve those standards. // Reintegration into the production line, before the operational step that determines the transformation of a previously transformed product or one to be transformed that left the production line.

**Requirements:** The criteria set down by the competent authorities relating to trade in fish and fishery products covering the protection of public health, the protection of consumers and conditions of fair trading.

**Residue:** The residue of pharmacological action substances, their transformation products, and other substances that are transmitted to animal products and that may be harmful to human health.

**Recall of Products from the Market:** Recalling products from the market is defined as an action to withdraw non-compliant products from distribution.

**Backflow:** Flow of water or other fluids, mixes or substances, to potable water distribution pipes, from the source or sources, different from the original sources.

**Back-siphonage:** Backflow of contaminated or used water, from a pipe, tank or another source to the potable water supply pipes, caused by the negative pressure produced in water supply pipes.

**Document Review:** Act of controlling that the products have the corresponding supporting information that accredits their possession, transfer and legal origin. This documentation can be related to taxes (waybills and invoices), customs (DIN, DUS-SED, B/L), health entities (sanitary certificates, Single Form for Customs Destination and/or Entry) and other legal origin accreditation documents (*Dissostichus* Catch Document, ICCAT Unloading Statistics Documents, EU Catch Certificate.)

**Labeling:** Set of inscriptions, legends or illustrations included in a label that provides information on the characteristics of a food product. Identification of a chemical product that includes at least the name of the product and the manufacturer, its use instructions, and the Public Health Institute authorization, accordingly.

**Label:** Tag, label, mark, image or other descriptive or graphic sign, that has been printed, stenciled, embossed, carved or attached to the food's packaging.

**SAG:** Agriculture and Livestock Service.

**Wholesomeness:** Characteristics of a product or process related to the contamination or salubrity of a product.

**Sanitation:** Proper treatment of surfaces that come into contact with food through an effective process to (a) destroy vegetative cells of microorganisms with an effect on public health; (b) substantially reduce the number of other unwanted microorganisms; (c) not affect the product adversely or its safety for the consumer.

**Sanitizer:** Chemical product authorized by the Ministry of Health, intended to eliminate or reduce potentially harmful bacteria on the surfaces that come into contact with food.

**Clean Area:** Physical area of a fish meal or fish oil plant which has facilities, equipment, and tools used for the transformation process and to handle, reprocess, transport and/or store a finished product.

**Dirty Area:** Those areas of the plant that are not part of the clean area.

**Selection:** Removing dead or unsafe bivalve mollusks from a certain lot.

**Seal:** Instrument used to apply a safeguard for transferring the resource, from the entry to the destination point.

**Bilge Waters:** The dirty water that collects in the bottom inside part of a vessel.

**SERNAPESCA Goods Entry System/SIMS:** Platform that allows customs agents and importers to declare the entry of goods under the Service's authority.

**Loading/Unloading Sites:** Infrastructure built to move loads from one place to another, including refrigerated loads.

**Sampling Request for Harvest:** Document that the staff in charge of the sanitary aspects of each farm must issue, and which contains the necessary information to conduct samplings for veterinary use pharmaceutical products residues control. This document also includes the Sample Delivery and Sampling Report Form.

**Sampling and Analysis Request for Export/SMAE:** Form issued by SERNAPESCA where the interested party requests a sanitary assessment of its product through an end product control to obtain sanitary certification.

**Single Entry Request/SUI:** A single form that allows requesting the authorization before the National Fisheries and Aquaculture Service to enter goods within the authority of this Service.

**Surfaces in Contact with Products:** Surfaces that come into direct contact with the end product or the raw material and those that drain over the product or over the surfaces that are in contact with them. These surfaces must consider kitchenware, processing equipment, conveyor belts, containers, bins, etc.

**Supplement:** Mix of two or more ingredients, with or without additives, capable of partially satisfying the nutritional requirements of the species for which they are intended.

**Surimi Base:** Chopped, cleaned, dried and refined fish flesh to which cryoprotectants are added to be then frozen. It is intended for the production of surimi-based products.

**Unauthorized Substance:** Those products or substances whose use is not registered or authorized by the competent authorities in aquaculture activities, having associated control mechanisms that tend to guarantee their absence as well as the absence of its residues in the finished product.

**Prohibited Substances:** Pharmaceutical products whose administration to animals is prohibited by the Chilean or destination market's legislation.

**Sample Size (n):** Set of products or primary packaging units that are extracted and that are representative of a lot, in which the corresponding analyses take place.

**Initial Temperature:** Mean temperature of the content of the coldest package, which will be processed at the moment in which the thermal process starts and is determined after the product is agitated inside the filled and sealed package. The coldest package means the first sealed package that will be subjected to a process in a certain autoclave. In the case of overpressure autoclaves with water immersion or water cascade, the coldest water temperature is when water is at a temperature lower than the first sealed package.

**Come up Time - CUT:** Time that elapses between the entrance of steam into the closed autoclave, until the set process temperature is reached.

**Transformation:** Fishery activity whose purpose is to manufacture products coming from any hydrobiological species, through partial or full processing of owned or foreign catches obtained in the extractive phase. The evisceration of caught fish, their preservation in ice, or the application of other preservation techniques of hydrobiological species shall not be understood as a transformation fishery activity. // Thermal and reduction treatment, validated and recognized by the National Fisheries and Aquaculture Service, for the production of fish meal or other protein concentrates including peptones, fish oil, and its by-products.

**Traceability:** Property of the result of a measurement whereby it can be related to stated measurement patterns, usually national or international standards, through an unbroken chain of measurements.

**Sampling Unit:** A set amount of product through which the unit for the sample is obtained.

**Primary Unit:** The minimum unit that can be separated from the lot, with or without primary packaging.

**Secondary Unit:** Corresponds to the packaging, usually boxes, which (secondary packaging) contains primary units.

**Validation:** A check before implementation, through objective evidence that supports that control parameters, preventive measures, and corrective actions are effective for the compliance of the objectives outlined in the HACCP plan.

**Air Gap:** The unobstructed vertical distance through the free atmosphere between the lowest opening from any pipe or faucet supplying water to a tank, plumbing fixture, or another device, and the flood level rim of the receptacle

**Vents:** Openings in the autoclave cover, controlled by gates or suitable valves used to discharge air. This discharge takes place at the beginning of the process at a time and temperature set by the Process Authority.

**Physical Verification:** Direct observation of fishery products, to determine if what is stated in the entry documents, regarding quantity, type of product and legal origin, matches the content of the load at the entry.

**Verification:** Application of different methods, procedures, trials and other evaluations different from monitoring, that allow determining if the HACCP plan is working as intended.

**Endorsement:** An action or procedure through which a National Fisheries and Aquaculture Service official accredits that the content of a document has a legal origin through its sealing and signing.

**Production Area:** Parts of the maritime, lake, estuarine areas containing natural beds of bivalve mollusks or sites in which live bivalve mollusks are cultivated or collected.

Relaying Area: Any sea, estuarine or lagoon area approved by the competent authority, with boundaries clearly marked and indicated by buoys, posts or any other fixed means, and used exclusively for the natural purification of live bivalve mollusks.

Areas not Subject to Marine Toxins: Geographic areas in which, historically, the presence of toxins has not been detected. They correspond to the following Regions: Arica and Parinacota, Tarapacá, Antofagasta, Valparaíso, O´Higgins, Maule, Bío-Bío, Araucanía and Los Ríos.

Areas Subject to Marine Toxins: Geographic areas in which, historically, episodes of marine biotoxins presence have occurred. They correspond to the following Regions: Atacama, Coquimbo, Los Lagos, Aysén, and Magallanes.

\*Translator’s note: The Glossary is not in alphabetical order in English, it follows the same alphabetical order of the original version in Spanish.